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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,155	04/08/2004	Leif Kongerslev	KONGERSLEV1	6668

1444 7590 07/24/2007
BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER

MOSHER, MARY

ART UNIT	PAPER NUMBER
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1609

MAIL DATE	DELIVERY MODE
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07/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/820,155

Applicant(s)

KONGERSLEV ET AL.

Examiner

Mary E. Mosher, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. ____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group II, species collectin, in the reply filed on October 11, 2006 is acknowledged. The traversal is on the ground(s) that "Traversal is based on allowability of a generic claim." This is not found persuasive because it does not distinctly and specifically point out the supposed errors in the restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

Claim 42 is objected to because of the following informalities: "elimination a microbial species" is grammatically incorrect – perhaps "elimination of a microbial species" is intended?. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 44-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 44-55 recite the limitation "the MBL". Claim 56 recites "the medicament." There is insufficient antecedent basis for these limitations in the parent claim 35.

Claims 32 and 35-66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

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invention. These claims are drawn to a body-treating method, for preventing or treating Severe Acute Respiratory Syndrome (SARS), where an effective amount of collectin is administered to an individual in need thereof. The specification states that maltose-binding lectin (MBL) binds to SARS coronavirus (SARS-CoV), and also states that MBL inhibits infection of cultured cells by SARS-CoV in a concentration dependent manner. No actual data is presented, but Moon et al (US 20040243601, not prior art) provides data confirming these assertions, see Figures 7 and 8 and example 5. However, the specification provides little guidance and no working example of a treatment method in an individual. In the SARS treatment art, in vitro culture inhibition studies did not effectively predict effective treatment in vivo, see as evidence the review by Stockman et al (PloS Medicine 3(9):1525-1532, e343, September 2006). See the discussion of ribavirin and IFN type I, for example. Therefore in vitro inhibition of infection is not accepted as predictive in the SARS art. Also, Leth-Larsen et al (Immunobiology 212:201-211, 2007) provides evidence that lung surfactant protein D, not serum MBL, selectively binds the SARS spike protein. Considering the limited guidance in the specification, the absence of working examples, the undeveloped state of the prior art, the unpredictability of the SARS treatment art, and the quantity of experimentation required to find effective treatment conditions, it is concluded that undue experimentation would be required to practice the invention as claimed.

Information Disclosure Statement

The information disclosure statement filed 10/6/2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each

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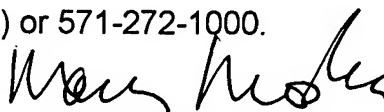
non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The publication by Janeway et al has not been considered, as only the title page and publisher's information was provided.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on varying dates and times; please leave a message.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Mary E Mosher, Ph.D.

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Primary Examiner
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7/9/07